K030212

MAR 27 2003

EXHIBIT A

510(k) Summary

Substantial Equivalence

In accordance with the requirements of 21 CFR § 807, this summary is formatted with the Agency's final rule ".... 510(k) Summaries and 510(k) Statements..." and can be used to provide equivalence summary to anyone requesting it from the Agency.

Manufacturer

Genzyme Biosurgery
A Division of Genzyme Corporation
600 Airport Road
Fall River, MA 02720-4740

Contact Person

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Date Prepared

March 21, 2003

Device Information

Trade Name:	Monodek™ Synthetic Absorbable Surgical Suture.
Common Name:	Polydioxanone Absorbable Surgical Sutures.
Classification Name:	Absorbable Polydioxanone Surgical Sutures

Indications for Use

Monodek™ Synthetic Absorbable Surgical Sutures are indicated for use in all types of soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur and opthalmic surgery. Monodek suture is not indicated in adult cardiovascular tissue, microsurgery and neural tissue. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to six weeks) is desirable.

Device Description

Monodek Absorbable Surgical Suture meets all USP requirements except for oversized diameter. Monodek is available in sizes 6-0 through 0 (metric sizes 0.7 through 3.5), undyed and dyed (violet). The suture is a sterile, monofilament and is provided in a variety of lengths, with or without needles and may be supplied in a variety of cut lengths or on ligating reels.

EXHIBIT A

510(k) Summary

Substantial Equivalence

The device is similar in intended use, materials, design, and performance characteristics to the currently cleared CP Medical Mono-Dox Absorbable Surgical Sutures (#K013274) and the currently approved Ethicon PDS II Absorbable Surgical Suture (PMA N18331).

The determination of substantial equivalence for this device was based on a detailed device description, performance testing and conformance with voluntary performance standards, e.g. ANSI/AAMI/ISO 10993-1 Biological Evaluation of Medical Devices, USP Section XXV - Absorbable Surgical Sutures, Guidance Document "Guidance for Surgical Suture 510(k) s" issued on August 10, 2000 and the FDA "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA", December 19, 2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 27 2003

Mr. Stephen Page
Director of Regulatory Affairs
Genzyme Biosurgery
600 Airport Road
Fall River, Massachusetts 02720-4740

Re: K030212
Monodek™ Synthetic Absorbable Surgical Suture
Regulation Number: 878.4840
Regulation Name: Polydioxanone Suture
Regulatory Class: II
Product Code: NEW
Dated: January 16, 2003
Received: January 21, 2003

Dear Mr. Page:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k)

premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known) K030212

Device Name: Monodek Polydioxanone Absorbable Surgical Suture

Indications for Use

Monodek™ Synthetic Absorbable Surgical Sutures are indicated for use in all types of soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur and opthalmic surgery. Monodek suture is not indicated in adult cardiovascular tissue, microsurgery and neural tissue. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to six weeks) is desirable.

(Please do not write below this line - Continue on another page if necessary)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR § 801.109)

(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K030212